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# Surgical Versus Balloon Therapy for Aortic Coarctation in Infants ≤3 Months Old

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***Objectives.*** This study compared the efficacy and safety of balloon angioplasty with surgical correction of native aortic coarctation in infants ≤3 months old.

***Background.*** There is a controversy with regard to the role of balloon angioplasty in the treatment of aortic coarctation, especially in young infants.

***Methods.*** Data from 29 infants ≤3 months old undergoing therapy for aortic coarctation during the decade ending 1992 were analyzed. Fourteen infants underwent surgery, and 15 had balloon angioplasty. The sole criterion for allotment to the balloon group was the availability of an interventional cardiologist at the time of presentation of the infant.

***Results.*** The surgical and balloon groups were comparable ($p > 0.1$) with regard to age (27 ± 35 [mean ± SD] vs. 29 ± 27 days), weight (3.5 ± 0.9 vs. 3.9 ± 1.0 kg) and prevalence (7 of 14 vs. 8 of 15) and type of associated defects. Operative (1 of 14 vs. 1 of 15) and late (3 of 13 vs. 3 of 14) mortality, immediate gradient relief (36 ± 25 to 10 ± 9 mm Hg vs. 41 ± 14 to 6 ± 6 mm Hg) and follow-up gradient (27 ± 27 vs. 24 ± 19 mm Hg) were similar ($p > 0.1$). Infants with a gradient >20 mm Hg at follow-up (6 of 13 vs. 7 of 14) and need for reintervention (6 of 13 vs. 7 of 14) were also similar ($p > 0.1$) in both groups. Duration of hospital stay during the first intervention was higher ($p < 0.05$) in the surgical (32 ± 37 days) than the balloon (7 ± 6 days) group. Similarly, duration of endotracheal intubation and mechanical ventilation was longer ($p < 0.05$) in the surgical (12 ± 16 days) than the balloon (2 ± 3 days) group. Complications after surgical intervention (0.86 events/patient) were higher ($p < 0.01$) than those seen after balloon angioplasty (0.27 events/patient). However, the lack of significant differences observed for mortality rates and residual gradients may be due to low statistical power to detect differences (16% to 49%), implying that this may be due to either actual lack of statistical difference or small sample size.

*Conclusions.* The data indicate that the degree of relief from aortic coarctation and the frequency with which reintervention is needed are similar in both groups. However, the morbidity and complication rates are lower with balloon than with surgical therapy. These data suggest that balloon angioplasty may be an acceptable alternative to surgical correction in the treatment of symptomatic aortic coarctation in infants ≤3 months old.

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The role of balloon angioplasty in the treatment of native aortic coarctation is controversial. Some workers (1–8) advocate balloon angioplasty, whereas others (9–11) are against it. Recommendations for the use of balloon angioplasty have also been diminished by reports of development of aneurysm at the site of coarctation dilation (12,13). In addition, there are limited data comparing surgical versus balloon therapy (14). In this study, we compared the safety and efficacy of balloon angioplasty with surgical correction of native (unoperated) aortic coarctation in infants ≤3 months old.

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## Methods

**Study group.** All infants ≤3 months old seen during the decade ending 1992 who underwent either surgical or balloon therapy for native aortic coarctation, irrespective of the associated defects were included in our analysis. Indications for intervention were congestive heart failure or hypertension not controlled with the usual medical management, or both. When hypertension was the sole criterion for intervention, blood pressure was higher than the 95th percentile for age. We excluded any patient undergoing additional procedures (with the exception of ligation of ductal structure and banding of the pulmonary artery) at the time of initial intervention (e.g., Norwood or Damus-Kaye-Stansel procedures). Twenty-nine infants met these criteria: 14 underwent surgical correction; 15 had balloon angioplasty. The sole criterion for allotment to the balloon group was the presence of the interventional cardiologist (P.S.R.) at the time that intervention was needed in a given patient. Conventional surgical techniques were used for relief of coarctation through left lateral thoracotomy. The balloon angioplasty



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technique has been described elsewhere (1–3,15) and is not reviewed here. Two neonates had balloon angioplasty performed through the umbilical artery (16). All infants were followed up clinically, and a repeat cardiac catheterization was performed when clinically indicated. For the assessment of recoarctation, peak to peak systolic pressure gradients obtained at cardiac catheterization were used when available. Peak systolic blood pressure difference between arm and leg pressures, simultaneously obtained by sphygmomanometry, was utilized if cardiac catheterization was not performed.

**Statistical methods.** Data are expressed as mean values ± 1 SD. For all statistical testing, $p < 0.05$ was significant, and two-tailed tests were used. The Student *t* test was used for comparison of mean values for continuous variables. Two-sample *t* tests were used to compare data between treatment groups. For tests assuming unequal variances, the approximate *t* test, which uses the unpooled estimate of variance and the Satterthwaite approximation for degrees of freedom, was performed. Paired *t* tests were used to assess changes before and after treatment within treatment groups. Categoric data were compared using the Fisher exact test.

## Results

**Patient characteristics.** The surgical group included 14 patients between 2 and 90 days old (mean age [±SD] 27 ± 35 days; 3.5 ± 0.9 kg, range 2.3 to 5.7). Significant associated defects were present in 7 (50%) of 14 patients and included large ventricular septal defects (three infants), severe aortic or subaortic stenosis (two infants), double-inlet left ventricle (one infant) and transposition of the great arteries with ventricular septal defect (one infant). Ten infants underwent resection and end to end anastomosis; two had subclavian flap angioplasty; and the final two had Gore-Tex interposition grafts put in to bypass the aortic obstruction. All patients had their ductal structure ligated, and four patients had additional banding of the pulmonary artery performed at the time of surgical correction of aortic coarctation.

The balloon angioplasty group included 15 patients between 3 and 90 days old (mean age 29 ± 27 days), not significantly different ($p = 0.864$) from that in the surgical group (Table 1). They weighed between 2.1 and 6.0 kg (mean weight 3.8 ± 1.0 kg), again, not different ($p = 0.404$) compared with the surgical group. Associated defects were present in 8 (53%) of 15 patients, not significantly different ($p = 0.873$) from that seen in the surgical group, and included large ventricular septal defect (three infants), severe aortic stenosis (two infants), double-inlet left ventricle (one infant), common atrioventricular canal with severe right dominance (one infant) and mitral and aortic stenosis with left ventricular hypoplasia (one infant) (forme fruste hypoplastic left heart syndrome). In addition, one infant presented with low (cardiac) output syndrome (16), and another had severe cardiomyopathic changes in the left ventricle (17).

**Table 1.** Patient Characteristics

| | Surgical Group (n = 14) | Balloon Group (n = 15) | p Value |
|---|---|---|---|
| Age (days) | | | |
| Mean ± SD | 27 ± 35 | 29 ± 27 | 0.864 |
| Range | 2–90 | 3–90 | |
| M/F | 8/6 | 9/6 | 0.877 |
| Weight (kg) | | | |
| Mean ± SD | 3.5 ± 0.9 | 3.8 ± 1.0 | 0.404 |
| Range | 2.3–5.7 | 2.1–6.0 | |
| No. of associated defects (%) | 7 (50%) | 8 (53%) | 0.873 |

F = female; M = male.

**Initial results.** In the surgical group, the peak systolic pressure gradient across the coarctation decreased from 36 ± 25 to 10 ± 9 mm Hg ($p < 0.005$) after surgery. Postoperative values were calculated from blood pressure measurements made 6 to 8 h after the infant had been returned to the intensive care unit. In the balloon angioplasty group, the peak to peak systolic pressure gradient across the coarctation decreased from 41 ± 14 to 6 ± 6 mm Hg ($p < 0.001$) immediately after angioplasty (Table 2). The postangioplasty pressure measurements were obtained by pressure pullback recordings 15 min after angioplasty.

The mean peak pressure gradients across the coarctation before and after intervention were not significantly different ($p > 0.1$) between the surgical and balloon groups (Table 2). The mean decrease in peak pressure gradient after interven-

**Table 2.** Results of Intervention

| | Surgical Group | Balloon Group | p Value |
|---|---|---|---|
| Peak to peak systolic pressure gradient (mm Hg) | | | |
| Before intervention (mean ± SD) | 36 ± 25 | 41 ± 14 | 0.508 |
| Immediately after intervention (mean ± SD) | 10 ± 9 | 6 ± 6 | 0.168 |
| No. (%) of pts with gradient >20 mm Hg | 1 (7) | 0 (0) | 0.301 |
| At follow-up (mean ± SD) | 27 ± 27 | 24 ± 19 | 0.740 |
| Range | 2–94 | 0–49 | |
| No. (%) of pts with gradient >20 mm Hg | 6 (46) | 7 (50) | 0.836 |
| No. (%) of pts needing additional intervention for recoarctation at follow-up | 6 (46) | 7 (50) | 0.836 |

pts = patients.

Table 3. Mortality, Morbidity and Complications After Intervention

| | Surgical Group | Balloon Group | p Value |
|---|---|---|---|
| Mortality | | | |
| Initial, no. (%) | 1 (7) | 1 (6.6) | 0.960 |
| Late, no. (%) | 3 (23) | 3 (21) | 0.925 |
| Morbidity | | | |
| Duration of hospital stay (days) | | | |
| Mean ± SD | 32 ± 37 | 7 ± 6 | 0.016 |
| Range | 7–90 | 2–25 | |
| Duration of mechanical ventilation (days) | | | |
| Mean ± SD | 12 ± 16 | 2 ± 3 | 0.025 |
| Range | 1–55 | 0–10 | |
| Complications (events/patient) | 0.86 | 0.27 | 0.004 |

tion was also not significantly different (p = 0.28) between the two groups (26 ± 26 vs. 35 ± 14 mm Hg for the surgical and balloon groups, respectively). After intervention, a peak systolic pressure gradient >20 mm Hg was present in 1 (7%) of 14 surgical group patients, whereas none of the 15 balloon group patients had gradients >20 mm Hg (p = 0.301).

**Initial mortality.** In the surgical group, one infant died 16 days after initial surgery after repeat surgery for recoarctation and surgical closure of ventricular septal defect. In the balloon angioplasty group, one infant with double-inlet left ventricle, l-transposition of the great arteries and severe obstruction at the bulboventricular foramen died 4 days after balloon angioplasty while waiting for surgical palliation. The initial mortality rates for both groups were comparable (p = 0.96).

**Morbidity and complications.** The duration of hospital stay varied between 7 days and 3 months (32 ± 37 days) in the surgical group, whereas in the balloon angioplasty group it varied between 2 to 25 days (7 ± 6 days); the latter is significantly shorter (p < 0.05) (Table 3). Although data on cost of hospital stay were not extracted, the cost as calculated on the basis of number of days of hospital stay and number of days in the intensive care unit, was significantly higher for the surgical than the balloon group.

Endotracheal intubation with mechanical ventilation was required in all patients for 1 to 55 days (12 ± 16 days; median 6 days) in the surgical group. In the balloon angioplasty group, mechanical ventilation was utilized in five patients for 2 to 10 days (2 ± 3 days for the entire balloon angioplasty group), significantly shorter (p < 0.01) than that required in the surgical group.

Significant complications occurred in 8 (57%) of 14 patients in the surgical group and included acute renal failure, central nervous system events (seizure in 1, right middle lobe infarction in 1), cardiac arrest, tension pneumothorax, septicemia and paradoxic hypertension in 2 patients each. In the balloon angioplasty group, femoral artery complications occurred in two infants (13%), and blood loss requiring blood transfusion occurred in two patients (13%). The complication rate was higher (p < 0.01) in the surgical (0.86 events/patient) than in the balloon (0.27 events/patient) group.

**Late mortality.** Three infants in the surgical group (23%) died 5 weeks, 3 months and 6 months, respectively, after surgical repair of coarctation. The first infant had poor left ventricular function and died after attempted relief of severe aortic stenosis. The second infant died after surgical palliation of double-inlet left ventricle with severe obstruction of the bulboventricular foramen. The third patient had severe tunnel subaortic stenosis and died after attempted repair. There were also three deaths (21%) in the balloon angioplasty group, not different (p = 0.925) compared with the surgical group. The first child had a large ventricular septal defect and died at home 2 months after angioplasty before a scheduled appointment for surgical correction. The other two infants died after palliation of forme fruste hypoplastic left heart syndrome 5 and 6 weeks after balloon angioplasty, respectively.

**Follow-up results.** The infants in the surgical group were followed up for 3 months to 9 years (median 4.5 years). Nine children were followed up >1 year; six of these were followed up >4 years. Residual gradient across the site of coarctation repair was measured at cardiac catheterization in 10 children, whereas sphygmomanometric blood pressure measurement was used in the remaining 3 children. Peak to peak gradient was 27 ± 27 mm Hg (range 2 to 94, median 22). Recoarctation defined as peak to peak gradient >20 mm Hg (18) was present in six children (46%). Balloon angioplasty was performed in five of these children, with a resultant decrease in peak gradient from 49 ± 31 to 12 ± 9 mm Hg (p < 0.01). The remaining child with recoarctation underwent surgical resection. Repeat intervention was performed 5 to 24 months (13 ± 9 months) after initial operation.

The infants in the balloon angioplasty group were followed up for 4 months to 8 years (median 4 years). Follow-up >1 year was available in 10 children; 6 of these had been followed up >4 years. Residual peak to peak gradients across the dilated coarctation were measured at cardiac catheterization in all patients and were 24 ± 19 mm Hg (range 0 to 49; median 19) and were not significantly different (p = 0.74) from those seen in the surgical group (Table 2). Recoarctation (peak to peak systolic pressure gradient >20 mm Hg) was present in 7 children (50%) and was not significantly different (p = 0.836) from that seen in the surgical group. Early in our balloon angioplasty experience, two infants underwent successful surgical correction of coarctation. The remaining five infants underwent repeat balloon angioplasty, with reduction of the gradient from 40 ± 9 to 10 ± 5 mm Hg (p < 0.01). Reintervention in the balloon group was performed 4 to 21 months (10 ± 5 months) after initial balloon angioplasty. A review of cineangiograms did not reveal any aneurysms in either the surgical or balloon angioplasty group.

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**Table 4.** Comparison of Mortality and Recoarctation Rates Between Surgical and Balloon Angioplasty Groups in Neonates and Infants <1 Year Old

| | Coarctation Surgery 1953 to 1991* | p Value | Balloon Angioplasty 1982 to 1991† | p Value | Coarctation Surgery 1979 to 1991‡ |
|---|---|---|---|---|---|
| Initial mortality rate | 617 (19%) of 3,292 | < 0.01 | 5 (7%) of 75 | > 0.1 | 82 (13.5%) of 607 |
| Late mortality rate | 483 (18%) of 2,645 | < 0.005 | 3 (4.2%) of 70 | < 0.01 | 66 (12.8%) of 517 |
| Recoarctation rate | 421 (17%) of 2,540 | > 0.1 | 14 (19%) of 75 | > 0.05 | 59 (11.4%) of 517 |

*Pooled data from 49 reports published since 1980. †Pooled data from published reports plus the authors' case material. ‡Pooled data from 11 reports of the results of coarctation surgery performed between 1979 and 1990. Modified, with permission, from Rao (19).

## Discussion

There does not appear to be a consensus with regard to the utility of balloon angioplasty in the treatment of neonates and young infants with symptomatic aortic coarctation. For this reason, we undertook this study to compare surgical therapy with balloon angioplasty. Both surgery and angioplasty produced a significant, immediate reduction in pressure gradient across the aortic coarctation, and the extent of relief of obstruction appeared to be similar. Initial and late mortality seen in the two groups appeared to be secondary to basic associated cardiac defects, not related to the type of intervention performed for relief of coarctation. At follow-up, residual gradients after both forms of therapy were similar. In addition, the incidence of recoarctation and need for reintervention were similar in both groups. Thus, immediate result and follow-up data attested to similar efficacy with both modes of therapy.

When morbidity, as assessed by duration of hospital stay and need for endotracheal intubation and mechanical ventilation, was compared, the surgical group had a higher morbidity rate than the balloon group. Similarly, the complication rate for the surgical group (0.86 events/patient) was higher than that in the balloon group (0.27 events/patient).

Thus, the effectiveness of relief (both immediate and at follow-up) and the mortality rates (both initial and late) appear to be similar with both modes of therapy. However, morbidity, as measured by duration of hospital stay and mechanical ventilation and the incidence of complications, appeared to be higher in the surgical group than in the balloon angioplasty group. On the basis of these data, we suggest that balloon angioplasty is an acceptable alternative to surgical correction in the treatment of symptomatic aortic coarctation in infants <3 months old.

**Study limitations.** This study was a retrospective analysis of patients undergoing therapeutic intervention. It has the drawbacks of any retrospective study, such as nonrandom assignment to treatment groups and number of patients available. Because the age and size of the patients, as well as associated defects, were similar in both groups, we believe that these data are valid and that recommendations based on these data are likely to be of value. Another potentially limiting factor is the number of available subjects. Calculations based on our sample size and previously published data indicate that the power to detect differences in mortality and morbidity rates and residual gradient is low (16% to 49%). Thus, the lack of statistically significant differences observed for mortality rate and residual gradient may be due either to an actual lack of difference or to lack of sufficient sample size to detect such a difference between treatment groups. The ideal way to test for differences in these variables would be to conduct a prospective, randomized study with a sample size large enough to ensure adequate power.

**Other studies.** Extensive review of published data did not reveal any studies comparing surgical correction and balloon intervention in neonates and infants. However, there was one study (14) in which 36 patients 3 to 10 years old were prospectively randomized to undergo either balloon angioplasty (n = 20) or surgical correction (n = 16). Similar immediate pressure gradient relief was observed in both groups. The risks of aneurysm formation and restenosis were higher in the angioplasty group, whereas risks of neurologic complication were higher in the surgical group. They concluded that balloon angioplasty for aortic coarctation may provide an effective initial alternative to surgical intervention in children beyond infancy and suggested that further follow-up was needed to evaluate the long-term risk of aneurysms after angioplasty.

In an attempt to evaluate the safety and efficacy of balloon angioplasty with surgical correction of aortic coarctation, we scrutinized 49 studies (published since 1980) reporting the results of surgical correction and 9 studies the results of balloon angioplasty in infants <1 year and compared them (4,19). In the surgical group, the investigators operated on 3 to 191 infants from 1953 to 1990. Associated significant cardiac defects were present in 2,106 (68%) of 3,075 infants with available data. The operative mortality rate varied between 0% and 50%, with an overall mortality rate of 19% (617 of 3,292) (Table 4). These investigators followed up 3 to 152 infants and observed a 3% to 59% late mortality rate. The average mortality rate was 18% (483 of 2,648 infants) during follow-up of 1 month to 25 years. Recurrence of coarctation ranged from 0% to 100%, with an average recurrence rate of 17% (421 of 2,540 infants) (Table 4). In an attempt to have comparable time periods during which both surgical and balloon interventions were performed, we examined the results in infants who underwent coarctation surgery between 1979 and 1990 (Table 4). The prevalence of associated significant heart defects was 70%

(360 of 516 infants), similar ($p > 0.1$) to the balloon angioplasty group, also with a 70% (45 of 64) prevalence. The mortality and recoarctation rates in these two surgical groups (49 reports published since 1980 and 11 papers in which surgical correction was performed between 1979 and 1990) were compared with pooled data from our balloon angioplasty experience plus nine balloon angioplasty reports dealing with infants <1 year old (Table 4). As can be seen, the mortality rates are higher with surgical correction than balloon angioplasty, whereas recoarctation rates are similar.

**Other issues.** In the presence of a widely open ductus, especially in infants receiving intravenous prostaglandin infusion, balloon angioplasty is technically difficult because the catheter tends to go into the ductus and pulmonary artery instead of the aortic arch and ascending aorta. In addition, the radial forces of balloon angioplasty may be dissipated, resulting in less successful balloon dilation of the coarcted segment. Because of these reasons, we discontinue prostaglandin infusion 6 to 12 h before the balloon angioplasty procedure, and we have not encountered problems with this approach.

**Conclusions.** Our data and that reviewed from the literature indicate that balloon angioplasty is effective in relieving aortic obstruction in the neonate and young infant with an acceptable complication rate, although the recoarctation rate is high. The latter can be relieved by repeat balloon angioplasty or surgical correction when the infant is in stable condition and less acutely ill. Although the effectiveness of balloon angioplasty is comparable to surgical correction, the morbidity is much lower than with surgical correction. For these reasons, we recommend balloon angioplasty as an effective alternative to surgical correction of symptomatic native coarctation in neonates and infants ≤3 months old.

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